REMARKS

Upon entry of this Amendment, claims 22-39, 48-52 remain in the application. New claims 53-58 have been added by this action. Claims 1-21 and 40-47 have been withdrawn from consideration by a previous action.

The present Amendment is submitted under the provisions of 37 C.F.R. 1.114. Entry and favorable consideration of this Amendment is earnestly sought.

The Applicants thank the Examiner for his continued attention in this matter and request that an interview be granted prior to entry of an Office Action in response to this Amendment.

Claims 22-39, and presumably claims 48 and 50 currently stand rejected under 35 U.S.C. § 102(e) as being anticipated by Liff (U.S. Patent No. 6,471,089). The Examiner indicates that the Liff reference discloses the drug dispensing system as described in claims 22, 31, 32, and 36 to include a controller (314), a reservoir of pharmaceutical (20) to be dispensed over time to a patient, the pharmaceutical including at least one of tablets, liquids, or gasses, to be administered in individual or discrete doses according to a treatment regimen (See column 1, last line, and column 2, lines 1-7 for "dispensing a pharmaceutical over time," and column 8, lines 16-20, for liquids and other forms of drugs being dispensed. See also column 2, lines 52-54, which indicate that each bottle contains a certain number of doses, which the Examiner construes as including one dose or several doses). The Examiner indicates that the system also includes a drug delivery mechanism (see references 5-6C) and a data network interface coupled to the controller (see Figure 13A). With regard to claims 23, 24, 31-34, 37, 38, and 39, the Examiner indicates that the Liff reference discloses sending messages to and from a health care service provider or drug supplier (see Figures 14T, for example), noting payers, doctors, inventory and refills having files for information pertaining thereto. The Examiner indicates that data messages identifying the patient and the identity of the particular drug are also disclosed in the Liff reference (see Figure 14K) for example. Pertaining to claim 25, the Examiner indicates that the

Liff reference discloses a human/display interface (see Figures 14A-14T). Pertaining to claims 26, 27, and 35, the Examiner indicates that the Liff reference discloses effecting payment for the provision of health care service or for a drug (see column 18, lines 14-17). Pertaining to claim 28, the Examiner indicates that the Liff reference discloses that the message is transported over the internet (see Figure 18). Pertaining to claim 29, the Examiner indicates that the Liff reference teaches that the message is transported via wireless (see column 8, line 24). Pertaining to claim 30, the Examiner indicates that the Liff reference discloses a pharmaceutical level detector (182) (see Figure 7C).

With regard to claim 48, the Examiner points to column 8, lines 16-20 as teaching one liquid material. With regard to claim 50, the Examiner indicates that claim 50 states that a memory is connected to the computer system. With regard to claim 51, the Examiner indicates that claim 50, column 18, lines 42-65 are anticipatory.

The Examiner indicates in the advisory action of September 9, 2003 that the claims as previously amended have been considered. However, the claims are not considered to overcome the Liff reference.

Claim 22 currently stands rejected under 35 U.S.C. § 102(e) as being anticipated by Liff. Claim 22 has been amended by this action to more particularly set forth the applicants' invention. The applicants' invention as set forth in claim 22, as amended, is directed to an intelligent drug dispensing appliance which includes a controller and a reservoir of pharmaceutical to be dispensed over time to an individual patient. The reservoir of pharmaceutical is located proximate to a patient at a location remote to a hospital. Support for this amendment is found in the specification as follows. The specification states at page 1, "Many individuals suffer from *chronic* health problems, the treatment of which requires many medication deliveries. Treatment regimens for diseases such as diabetes, asthma, epilepsy, cancer, and even allergies, require delivery of precise amounts of medication for the patient's survival. Treating chronic medical disorders often requires administration of medication over a long period of time and, according to a treatment regimen specified by a medical professional, such as a physician." (page 1, lines 14-19, emphasis added) It is submitted that the term "chronic

illness" supports the fact that this device is configured and oriented to be employed in non-hospital settings as significant amounts of time are spent away from hospital settings. Furthermore, treatment of diseases such as diabetes, asthma, epilepsy, and allergies, also supposes that the device will be one which includes a reservoir proximate to the patient. Thus, it is submitted that the applicants' invention as set forth in claim 22 as amended is supported in the specification.

Claim 22 as amended also specifies that the pharmaceutical as dispensed includes at least one of individual tablets, liquids, gasses, to be administered to an individual in individual doses according to a treatment regimen for direct use by the patient. Precise amounts of liquids noted and discussion of inhalable agents is taken as inferential support for infer direct use by the individual. The intelligent drug dispensing appliance of the present invention as set forth in claim 22 also includes a drug delivery mechanism responsive to the controller and coupled to the reservoir which is capable of controllably dispensing a pharmaceutical to an individual patient from the reservoir in a precise amount in response to signals from the controller. A further component of the intelligent drug dispensing appliance is a data network interface coupled to the controller.

As previously discussed, the Liff reference is directed to an automated pharmaceutical delivery system that is uniquely designed for the automated dispensing of *packaged* pharmaceuticals (see column 2, lines 20-40 and drawing figures 3, 5, 6A, 6B, 6C, 13J (reference numerals 399 and 404) 14, 15, 25, 26, 27. It is respectfully submitted that the reference fails to teach or suggest a device capable of administering precise unitized doses of at least one of tablets, liquids, gasses in individual doses to an individual patient according to a treatment regimen for direct use.

It is also submitted that the main teaching of the Liff reference is not directed to a system which provides a solution for "unit dose dispensing for individual patients". The Liff system is directed to a device which appears to possess the necessary mechanisms to introduce a plurality of doses into a dose container, seal the dose container, and dispense the container to an individual such as patient. The device specifically taught

and disclosed in Liff specifically requires the ultimate dispensing of material contained in bottles or containers and lacks the teaching or suggestion of dispensing for direct use or consumption by an individual patient on a unit dose basis as set forth in the Applicants' invention as defined in claim 22.

The Examiner also indicates that the Liff reference also teaches a device for dispensing drugs in unit doses for individual patient use as well as billing of weekly and monthly prescriptions. The Examiner cites column 1, line 67 to column 2, lines 1-8 to support this position. Turning to the background section of the Liff reference indicated by the Examiner, we find a discussion of automated pharmaceutical delivery systems which falls into three categories: automated devices in central pharmacy areas; automated devices in the patient care unit; and point-of-care information systems (see column 1, lines 33-36). The patient-care unit-based devices discussed are those that replace the traditional manual unit dose cart filling and delivery system. See column 1, lines 44-45. It is submitted that dose carts are devices typically found in institutional settings such as hospitals. These point-of-care systems contemplated in the background of the Liff reference are designed to enable immediate exchange of patient data *at the bedside* (column 1, lines 54-55). This also assumes hospital settings The background also states that "the above-described systems offer solutions for medication management in large hospitals where the large expense associated with large centrally-located pharmacy systems, decentralized patient care units, and point-of-care systems at the bedside are justifiable for unit dose dispensing and verification" (column 1, lines 63-67). It can be seen from the foregoing that the systems discussed in Liff as patient-centered or point-of-care systems are those which can be employed in a hospital setting. It is submitted that the background reference falls to teach or suggest a system for individual dose delivery that can be employed in a non-hospital setting proximate to a patient. The Liff reference indicates that one of the primary disadvantages of point-of-care systems is the high cost associated with placement of hardware in each room and networking the system (column 1, lines 58-60). Thus, It is submitted that the system referenced in the background of the Liff patent does not contemplate the decentralized system disclosed in the present invention.

The Applicants' invention as set forth in claim 22 and subsequent claims is directed to a system which can be employed proximate to a patient in non-hospital settings for the treatment of chronic illness. Such non-hospital settings can include the patient's home or domicile. It can be readily appreciated that a system such as that contemplated in the present invention can promote patient compliance in a drug-taking regimen without requiring hospitalizations or the like. One important area of non-compliance is the failure of patients to maintain adequate supplies of the required pharmaceuticals. This situation is particularly apparent in homebound patient populations who are unable to easily travel to a physician or a pharmaceutical dispensing entity to obtain new prescriptions or prescription refills of vital pharmaceuticals. Such populations include the disabled, senior citizens, as well as individuals undergoing aggressive home-based therapies and treatment regimens such as many types of cancer protocols and the like. It is respectfully submitted that neither the background nor the invention disclosed in Liff provides anticipatory support for the invention as set forth in claim 22. For these reasons, it is submitted that the Applicants' invention as set forth in claim 22 is not taught, anticipated, or rendered obvious by the Liff reference.

Claims 23-30 currently stands rejected under 35 U.S.C. § 102(e) as being anticipated by Liff. It is submitted that the applicants' invention as set forth in claims 23-30 depend either directly or indirectly from claim 22 to contain all of the limitations found therein. By this dependency, it is submitted that the applicants' invention as set forth in claims 23-30 is not taught, anticipated, or rendered obvious by the Liff reference by the reasons discussed previously in conjunction with claim 22.

Claim 31 currently stands rejected under 35 U.S.C. § 102(e) as being anticipated by Liff. Claim 31 has been amended by this action to more specifically set forth the applicants' invention. The applicants' invention as set forth in claim 31, as amended, is directed to an intelligent drug dispensing system providing replenishment of pharmaceutical medication. The system comprises an intelligent drug dispensing appliance that includes a data network interface, a controller, and a reservoir of

pharmaceutical to be dispensed to an individual patient. The reservoir is located proximate to the patient at a non-hospital location. The pharmaceutical includes at least one of individual tablets, liquids, and gasses to be administered in individual doses according to a treatment regimen for direct use. It is respectfully submitted that the Liff reference fails to teach or suggest a device whereby at least one of individual tablets, liquids, and gasses can be administered in individual doses for direct use by the patient at non-hospital locations. Thus, it is submitted that the applicants' invention as set forth in claim 31 is not taught, anticipated, or rendered obvious by the Liff reference.

Claim 32 currently stands rejected under 35 U.S.C. § 102(e). Claim 32 has been amended by this action to more specifically define the applicants' invention. Claim 32, as amended, is directed to an intelligent drug dispensing system providing replenishment of pharmaceutical medication. The system includes an intelligent drug dispensing appliance having a data network interface, a controller, and a reservoir of pharmaceutical including at least one of individual tablets, liquids, and gasses, to be administered in individual precise unit doses for direct use by the patient. The reservoir is located proximate to the patient in a non-hospital location. It is respectfully submitted that the Liff device fails to teach or suggest a reservoir of pharmaceutical to be dispensed to a patient which includes at least one of individual tablets, liquids, and gasses to be administered in individual doses for direct use by the patient in a non-hospital location. For this reason, it is submitted that the applicants' invention as set forth claim 32 is not taught, anticipated or rendered obvious by the Liff reference.

Claims 33-35 also stand rejected under 35 U.S.C. § 102(e) as being anticipated by Liff. The applicants' invention as set forth in claims 33, 34, and 35 depend directly from either claim 31 or claim 32 to contain all of the limitations found therein. By this dependency, it is submitted that the applicants' invention as set forth in claims 33, 34, and 35 is not taught, anticipated, or rendered obvious by the cited references for the reasons discussed previously in conjunction with claims 31 and 32.

Claim 36 stands rejected under 35 U.S.C. § 102(e) as being anticipated by the Liff reference. Claim 36 has been amended by this action to more specifically define

the applicants' invention. The applicants' invention as set forth in claim 36, as amended, is directed to an intelligent drug dispensing system providing automatic replenishment of pharmaceuticals which comprises a pharmaceutical replenishment request data server operatively coupled to a data network so as to receive pharmaceutical replenishment request messages from at least one intelligent drug dispensing appliance. The intelligent drug dispensing appliance includes a controller and a reservoir of pharmaceutical to be dispensed over time to a patient in a plurality of discrete doses for direct use by the patient. The reservoir is located proximate to the patient at a non-hospital location. It is respectfully submitted that the Liff reference fails to teach or suggest the dispensation of pharmaceutical to a patient in a plurality of discrete doses for direct use in a non-hospital location. Thus, it is submitted that the applicants' invention as set forth in claim 36 is not taught, anticipated, or rendered obvious by the Liff reference.

Claims 37, 38, and 39 also stand rejected under 35 U.S.C. § 102(e) as being anticipated by the Liff reference. Claims 37, 38, and 39 depend from claim 36 to contain all of the limitations found therein. By this dependency, it is submitted that the applicants' invention as set forth in claims 37, 38, and 39 is not taught, anticipated or rendered obvious by the Liff reference for the reasons discussed previously in conjunction with claim 36.

Claim 48 currently stands rejected under 35 U.S.C. § 102(e) as being anticipated by Liff. The Examiner indicates that the Liff reference teaches that the pharmaceutical is at least one liquid material and references column 8, lines 16-20. It is respectfully submitted that the Liff reference is directed to a device for dispensing packaged pharmaceuticals. The Liff reference specifically states that the "rack 34 can be modified to provide for a diversity of packages including various box and bottles sizes, end-of-use packaging, liquids, syringes, and various nonprescription products, for example medical supplies." It is respectfully submitted that the Liff reference refers to packaged materials rather than individual doses that are suitable for direct use by a patient at non-hospital, home-based settings such as inhalation doses and the like. For this reason, it is

submitted that the applicants' invention as set forth in claim 48 is not taught, anticipated, or rendered obvious by the cited reference.

Claims 50 and 51 currently stand rejected under 35 U.S.C. § 102(e) as being anticipated by Liff. Claims 50 and 51 depend, either directly or indirectly, from claim 22 to contain all of the limitations found therein. By this dependency, it is submitted that the applicants' invention as set forth in claims 50 and 51 is not taught, anticipated, or rendered obvious by the Liff reference for the reasons discussed previously in conjunction with claim 22.

Claim 49 currently stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff in view of Monkhouse (US Patent No. 6,514,518 B2). The Examiner indicates that the Liff reference generally discloses the drug dispensing system. Monkhouse is cited as disclosing a drug delivery mechanism including an inkjet printhead capable of delivering precise amounts of liquid. The Examiner indicates that the "binder" discussed in Monkhouse is a liquid binder and therefore should be construed as applicable. It is the Examiner's contention that, at the time of the invention, it would have been obvious to one ordinarily skilled in the art to have coupled the ink printer drug dispensing device of Monkhouse to the network system of Liff. It is respectfully submitted that the Monkhouse and Liff references taken together or separately fail to teach or suggest the administration of liquid material from an inkjet printhead in a manner capable of direct ingestion by a patient. It is further submitted that the Liff reference is primarily directed to packaged drug materials and directs the skilled artisan away from a device used for dispensing unit doses at a location remote to a hospital. The Monkhouse reference is directed to a solid free form fabrication system. The solid free form fabrication system disclosed in the Monkhouse reference is relatively bulky, cumbersome, and expensive, and, thus, would not be readily employed for use in a device which is capable of dispensing pharmaceuticals for direct use by an individual patient in a non-hospital location.

Claim 52 currently stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff in view of O'Brien. Claim 52 depends directly from claim 51 and

includes the limitations previously found in Claims 48, 49, and 22. By this dependency, it is submitted that the applicants' invention as set forth in claim 52 is not taught, anticipated or rendered obvious by the cited references for the reasons discussed previously in conjunction with claim 22.

New claims 53-58 have been added by this action. New claim 53 is directed to an intelligent drug-dispensing appliance that includes a controller, a reservoir of pharmaceuticals specific to the individual patient to be dispensed over time and a drug delivery mechanism located proximate to the patient at a location remote to a hospital. The drug delivery mechanism is coupled to and responsive to the controller and to the reservoir to dispense the pharmaceutical to the patient from a reservoir in a precise amount in response to signals from the controller. The device also includes a data network interface coupled to the controller. Support for the controller, reservoir, and data network interface are found in previously presented claims. Support for the drug dispensing mechanism is found in Figure 1 at reference 108. It is submitted that the cited references fail to teach or suggest a drug dispensing mechanism located proximate to the patient in a location remote to a hospital. Thus, it is submitted that Applicants' invention as set forth in claim 53 is not taught, anticipated, or rendered obvious by the cited references.

Claim 54 is newly presented to depend from claim 53. Support for claim 54 is found previously in claim 22.

Claim 55 depends from claim 53 to specify that the device further includes a human/display interface which includes at least one of a tactile input device or a speech recognition device operatively coupled to the controller. Support for new claim 55 is found in the specification at page 3, lines 23-32 to page 4, lines 1-7.

New claim 56 depends from claim 53 to specify that the device includes at least one sensor operatively coupled to the controller which is capable of providing data signals indicative of the patient's physical condition. Support for claim 56 is found on page 3 of the specification at lines 16-22.

New claim 57 depends from claim 53 to specify that the intelligent drug dispensing appliance further comprises a pharmaceutical depletion guard which includes a pharmaceutical level detector coupled to the processor and the data network interface. The data network interface is capable of sending a message to at least one healthcare provider or pharmaceutical supplier that can include at least one of patient identity, pharmaceutical identity, and treatment regimen. Support for pharmaceutical depletion guard is generally found in the specification at page 2, lines 30-31, and page 4, lines 12-23.

New claim 58 depends from claim 57 that the data network interface of the intelligent drug dispensing appliance is capable of sending a data message to effect payment for a service, the service including at least one of the provision of health care and the provision of a pharmaceutical. Support for claim 58 is previously found in claim 26.

In summary, claims 22, 31, 32, and 36 have been amended. New claims 53-58 have been added. Discussion has been presented as to why the applicants' invention as set forth in claims 22-38 and 48-52 and new claims 53-58 is not taught, anticipated, or rendered obvious by the cited references. It is respectfully submitted that, in view of these actions, applicants' invention as set forth in claims 22-39 and 48-58 is not taught, anticipated, or rendered obvious by the cited references. It is further submitted that the applicants' invention as set forth in these claims is in condition for allowance. A notice of allowance is, therefore, respectfully requested. In the alternative, entry of this amendment for purposes of appeal is earnestly sought.

The Applicants respectfully request that the Examiner grant an interview in the above-identified matter prior to establishing an office action in response to this amendment. It is respectfully submitted that an interview can facilitate prosecution in this matter and resolve issues for further consideration. Thus, the Applicants' respectfully request the examiner grant the courtesy of an interview in this matter.

Respectfully submitted,

Denise M. Glassmeyer
Attorney for Applicant
Registration No. 31,831
(248) 649-9900

Date: September 24, 2003
3331 West Big Beaver Road
Suite 109
Troy, Michigan 48084-2813
DMG/ljo